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INTERVERTEBRAL DISK PROSTHESIS

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INTERVERTEBRAL DISK PROSTHESIS

[Prothèse de disque intervertebral]

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The invention concerns a device for an intervertebral disk prosthesis, more specifically /1* designed for the lumbar zone of the vertebral column of the human body, the device including two capsules with variable volume.

Degeneration of the intervertebral disks in the lumbar region of the vertebral column of the human body, in particular between vertebrae L4-L5 and L5-S1 may lead to disabling situations requiring the removal of the disk. Then it is necessary either to block the pair of vertebra in question to prohibit any relative movement (arthrodesis) or the replace the disk by a prosthesis.

Devices are known that form intervertebral disk prostheses, such as that described in the document EP0304305, composed of two deformable cylindrical capsules from inert composite fibers, the capsules containing a thixotropic gel and each being connected to a reservoir closed by a self-sealing membrane. These independent capsules are introduced empty or each partially filled in the drilling made approximately parallel to the vertebral plates in the deteriorated disk left in place, the gel next being introduced into each capsule with the aid of a syringe perforating

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* [Editor's note: numbers in the right margin represent pagination in the original foreign text.]

the membrane of each reservoir. The drawbacks of this device are numerous and we will mention several of them. Since the original intervertebral disk is perforated it loses the main part of its resistance characteristics, imposing on the capsules the entire transmission of forces, in particular compression forces for which various trials and measurements have shown that it reaches and exceeds 350 daN in the lumbar zone. These forces induced pressures in the gel greater than 100 b which cannot be supported by the self-sealing membranes. Once the capsules are in position functioning at constant volume, they may only be able to allow a small amplitude of relative movement of the adjacent vertebrae, very far from the normal amplitude.

The invention proposes to find a remedy for these drawbacks by proposing a intervertebral disk prosthesis device, more specifically designed for the lumbar zone of the vertebral column of the human body, formed from two deformable capsules arranged in the intervertebral space symmetrically with respect to the median sagittal plane of adjacent /2
vertebrae, the volume of the capsules may be reduced to facilitate the introduction, characterized in that each capsule is formed from two rigid plates, parallel in the absence of exterior constraints, provided with a means for anchoring in adjacent vertebrae and connected by a deformable casing so as to form an impermeable chamber with variable volume, each chamber being filled with a fluid with low compressibility.

The invention also proposes that the deformable casing is formed from a double wall, the interior wall being formed by a multiple ply bellows, the exterior wall being formed by a single ply bellows, the interior wall and the exterior wall may be formed from different materials.

Another characteristic of the invention is that for each capsule, means are provided to limit the relative displacements of the plates, these means being situated within each impermeable chamber. In one possible form of the embodiment, the means are formed for a plate by a cylindrical protuberance with a circular base inserting in a cylindrical housing with a circular base of another plate, radial play being provided to allow relative angular displacement and a variation in distance of the plates. In another possible form, the means are formed by a ball connected to one of the plates, this ball inserting in a cylindrical housing with a circular base of the other plate, play being provided to allow a variation in distance of the plates.

The invention is also characterized in that one of the two plates forming each capsule is provided with a means for filling, emptying and sealing the chamber. In a preferential form, the means are formed by a duct laid out in the bulk of the plate, this duct opening with one of its ends in the chamber and with the other end towards the exterior, this latter end being provided with a plug, the duct being provided with a check valve prohibiting the backflow of the fluid outside the chamber, the valve being able to be deactivated to empty the chamber.

Another characteristic of the invention is that the deformable casings are connected by /3
welding or by bonding on the plates.

The invention is even characterized in that the fluid with low compressibility is obtained by the mixture of a liquid and a gas slightly soluble in the liquid.

Lastly, the invention provides that two capsules may be connected through their plates, the two plates possessing ducts rigidly connected together, and that the ducts may be connected to ensure free intercommunication between the two chambers.

A preferential form of the invention is described below with reference to the attached drawings.

Figure 1 represents a capsule after cutting in the transverse plane.

Figure 2 represents two capsules including rigidly connected plates.

In reference to Figure 1, the entire capsule is formed from two plates 2 and 3 in the shape of disks with surfaces parallel to axis 4, provided with a means of anchoring known in itself (not represented) to ensure cohesion with the vertebral plates of adjacent vertebrae and combined by a deformable casing 5 formed from two walls 5e and 5f generally cylindrical in shape with a circular base with axis 4 by collar means 5a and 5b connected on the plates thus forming a impermeable chamber with volume 10. The deformation of the casing in the preferential direction of axis 4 is obtained in a way known in itself by forming of ply 5c of the interior wall and a single ply of the exterior wall. The geometry of the casing so obtained allows a variation in the space between plates 2, 3 and at the same time an angular variation between these same plates which may then withstand nonparallelism. The materials used must obviously be biocompatible, such as the stainless steel alloys 316 LVM, the titanium-vanadium-aluminum or cobalt-chromium alloys.

So as to relieve the casing from a transverse shearing constraint which would result from relative displacement of the plates parallel to their surfaces in the opposite direction, plate 2 is provided with a cylindrical rod 6 ending with a ball 7 with axis 4, the diameter of which is greater than the diameter of the rod 6, the ball 7 inserting in the cylindrical housing 8 with axis 4 adjoining plate 3. This antishearing device allows a variation in the distance of plates 2 and 3 where the minimum is imposed by the choice of the distance D between the ball 7 and the base of the housing 8. It also allows any rotation movement around the center 7a of the ball 7. The cohesion of the movements enables support of the relative displacement of adjacent vertebrae. Since the antishearing device is housed within the impermeable chamber 10, the particles that result from the unavoidable wear and tear of the device cannot be distributed in the body. In another possible form of the invention, the ball is replaced by a cylindrical body inserting in housing 8 with radial play being provided between the cylindrical body and the housing to allow angular displacements between the two plates. /4

To allow the entire unit of the two capsules to support the compression forces which tend to bring the two adjacent vertebrae together and to support the angular deviations between the

vertebral plates, volume 10 is filled with a fluid with low compressibility making it possible to restore the function of shock absorption ensured by the healthy intervertebral disk and allowing a variation in distance between plates 2 and 3. The level of compressibility is controlled by the proportion of the mixture of liquid and a gas that is not soluble in the liquid.

The plate 2 comprises a duct 9, the end of which opening on the exterior is closed by a plug 14. The duct 9 opens in the volume 10 by an orifice 11. Between the orifice 11 and the plug 14 is placed a bead 12, pushed by a spring 13 on a seat 12a, the entirety forming a check valve prohibiting fluid contained in volume 10 from being evacuated when the plug 14 is removed. A device (not represented) for introduction or evacuation of the liquid or gas contained in volume 10 is fixed in position with the plug 14 and comprises a protuberance moving the bead 12 away from its seat 12a thus deactivating the check function.

Figure 2 shows the two capsules connected rigidly by their homologous plates. The connection may be dismantled by known means not represented. A duct 17a combines the two ducts 17 and 17b thus ensuring intercommunication of volumes 16 and 16a through orifices 15 /5
and 15a. After filling with the slightly compressible fluid, the shock absorber function is conserved while the relative angular displacement of the plates in the transverse direction is increased relative to that which is obtained with two independent capsules.

Two capsules that may or may not be connected are positioned between the vertebral plates symmetrically on the median sagittal plane of the vertebrae. To facilitate this introduction, the volume 10 is partially filled with slightly compressible fluid. After positioning, the remainder of the fluid is introduced, thus restoring the intervertebral space and ensuring anchoring of the plates in the vertebrae. The presence of the exterior wall 5e protects the surrounding tissues from deterioration which could be caused by bringing the ply 5c closer together during deformation of the casing 5 and releasing of fluid which could result from a leak in the interior wall. The interior wall ensures the resistance to pressures prevailing in volume 10 while functioning and is made from a more resistant material than the exterior wall that has only the role of a screen.

Claims /6

1. Intervertebral disk prosthesis device, more specifically designed for the lumbar zone of the vertebral column of the human body, formed from two deformable capsules arranged in the intervertebral space symmetrically with respect to the median sagittal plane of adjacent vertebrae, the volume of the capsules may be reduced to facilitate the introduction, characterized in that each capsule is formed from two rigid plates, parallel in the absence of exterior constraints, provided with means for anchoring in adjacent vertebrae and connected by a deformable casing so as to form an impermeable chamber with variable volume, each chamber being filled with a fluid with low compressibility.

2. Device according to Claim 1 characterized in that the deformable casing is formed from a double wall, the interior wall being formed by a multiple ply bellows, the exterior wall being formed by a single ply bellows, the interior wall and the exterior wall may be formed from different materials.

3. Device according to Claim 2 characterized in that the interior wall and the exterior wall are formed from different materials.

4. Device according to Claim 1 characterized in that for each capsule, means are provided to limit relative displacements of the plates, these means being situated within each impermeable chamber.

5. Device according to Claim 1 characterized in that for each capsule, means are formed for a plate by a cylindrical protuberance with a circular base being inserted in a cylindrical housing with circular base of another plate, the radial play being provided to allow relative angular displacement and variation in distance of the plates.

6. Device according to Claim 4 characterized in that the means are formed by a ball connected to one of the plates, this ball being inserted in a cylindrical housing with circular base of the other plate, play being provided to allow a variation in distance of the plates.

7. Device according to Claim 1 characterized in that one of the two plates forming each capsule is provided with means for filling, emptying and sealing the chamber.

8. Device according to Claim 7 characterized in that the means are formed by a duct laid out in the volume of the plate, this duct opening with one of its ends in the chamber and with the other end towards the exterior, this latter end being provided with a plug, the duct being provided with a check valve prohibiting the backflow of the fluid outside the chamber, the valve being able to be deactivated to empty the chamber. /7

9. Device according to Claim 1 characterized in that the deformable casings are connected by welding on the plates.

10. Device according to Claim 1 characterized in that the deformable casings are connected by bonding on the plates.

11. Device according to any one of the preceding claims characterized in that the fluid with low compressibility is obtained by the mixture of a liquid and a gas slightly soluble in the liquid.

12. Device according to any one of the preceding claims characterized in that two capsules may be connected through their plates, the two plates possessing ducts rigidly connected together.

13. Device according to Claim 12 characterized in that the ducts are combined to ensure free intercommunication of the two chambers.

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FIG. 1

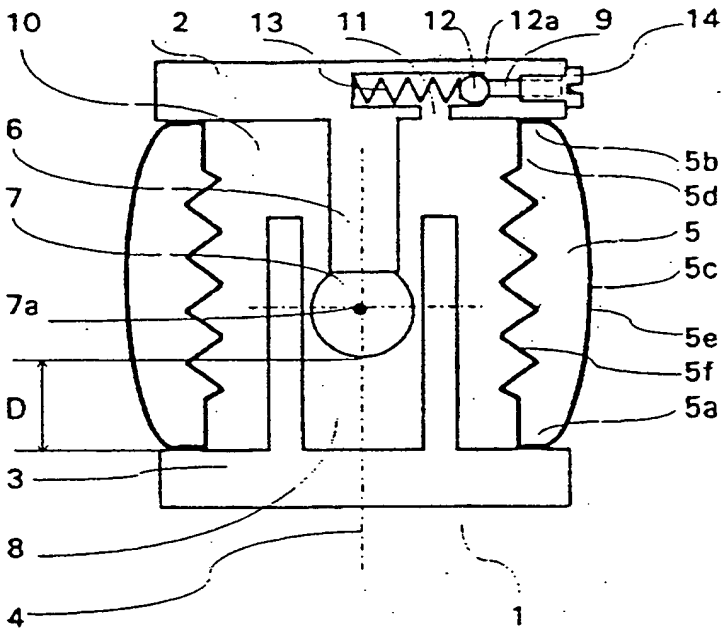

FIG. 2